

FEB 23 2006

1/3 K060150

510(K) SUMMARY

Andante Medical Devices LTD.

SmartStep™ System

7.1.1 Applicant's Name:

Andante Medical Devices Ltd.
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7.1.2 Contact Person:

Dorit Winitz, Ph. D
Biomedical Strategy (2004) Ltd.
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Ramat Gan 52520, Israel
Tel: +972-3-612-3281
Fax: +972-3-612-3282
dorit@ebms.co.il

7.1.3 Date Prepared:

January, 2006

7.1.4 Trade Name:

SmartStep™ System/ SmartStep™ Clinic System

7.1.5 Classification Name:

Device, Warning, Overload, External

7.1.6 Classification:

Class II; Product Code IRN;
Regulation No. 890.5575

7.1.7 Predicate Devices

Andante SmartStep™ System (K023161)

7.1.8 Device Description:

The SmartStep™ System is a monitoring & biofeedback system for gait training and re-education. The device is a tool, which is intended to assist the clinicians to accurately assess patients who are undergoing weight bearing restrictions and gait therapy training.

The SmartStep™ is used to measure the amount of weight being applied to an affected limb, to teach and promote specific weight bearing skills and to test patient's ability to maintain a weight bearing range.

The SmartStep™ system is to be used under the supervision of physician or licensed health care provider such as physiotherapist.

The SmartStep™ System is comprised of the following three main sub-elements:

- Flexible Insole that is placed in the patient's shoe, acting as a pressure-sensing element.
- Control Unit, connected to PC Software.
- PC Software that acts as a patient medical record and patient assessment tool.

A Manual Pump is used to inflate the Insole compartments.

7.1.9 Intended Use:

The SmartStep™ System is intended to sense the amount of weight applied to the planter surface of the foot during rehabilitation. The System alerts the user and/or therapist with alarm when the weight exceeded the pre-selected value. Furthermore, the SmartStep™ System is intended to be used in any situation in which therapist and/or patient would benefit from objectively assessing the amount of weight that is being applied to a lower limb.

7.1.10 Performance Standards:

No performance standards have been established for such device under Section 514 of the Federal Food, Drug, and Cosmetic Act. However, the SmartStep™ System complies with the voluntary standards such as IEC 60601-1, IEC 60601-1-2, AAMI/ISO 14971-1, and with the FCC requirements of CFR, parts 15, Subparts B & C.

7.1.11 Performance Data & Substantial Equivalence

The SmartStep™ System is substantially equivalent in all aspects, e.g., technological characteristics, mode of operation, performance characteristics, intended use, etc., to the commercially available SmartStep™ System. The principle changes between the devices include:

1. Control Unit

- 1.1 The design of the Control Unit was changed to improve its ergonomic design and to enable a wireless operated unit.
- 1.2 Inflation connectors were added to the Control Unit to enable on-line monitoring of the inflation status.
- 1.3 The operation modes were re-organized and the vibration feedback was eliminated.
- 1.4 Fault-condition indications and battery automatic shut-off capability were added.
- 1.5 Part of the electronic components of the Control Unit, such as microcontroller, battery and charger, were changed to improve device performance and reliability.

2. Manual Pump

The insole inflation pump was improved to include a Manual Pump rather than a syringe.

3. Software and User Interface

- 3.1 The PC User Interface was improved to include more intuitive, simple and clear GUI and to support multilingual User Interface.
- 3.2 Several functions and options were added to the PC Software.
- 3.3 The Software (PC and Control Unit) as a whole has been upgraded.

Electrical and electromagnetic testing and verification and validation testing of the Software were performed to ensure that the modified SmartStep™ System does not raise any new questions of safety and efficacy. Based on these tests results, Andante Medical devices Ltd. believes that the modified SmartStep™ System is substantially equivalent to the cleared SmartStep™ System, without raising new safety and/or effectiveness issues.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Andante Medical Devices Ltd.
C/O Dorit Winitz, Ph.D
Biomedical Strategy (2004) Ltd.
Moshe Aviv Tower, 34th floor
7 Jabotinsky Street
Ramat, Gan 52520, Israel

Re: K060150

Trade/Device Name: SmartStep™ System/ SmartStep™ Clinic System
Regulation Number: 21 CFR 890.5575
Regulation Name: Powered External Limb Overload Warning Device
Regulatory Class: II
Product Code: IRN
Dated: January 15, 2006
Received: January 28, 2006

Dear Dr. Winitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

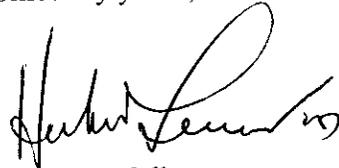
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



 Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1/1

K060150

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: SmartStep™ System/ SmartStep™ Clinic System

Indications for Use:

The SmartStep™ System/ SmartStep™ Clinic System is intended to sense the amount of weight applied to the planter surface of the foot during rehabilitation. The System alerts the user and/or therapist with alarm when the weight exceeded the pre-selected value. Furthermore, the SmartStep™ System/ SmartStep™ Clinic System is intended to be used in any situation in which therapist and/or patient would benefit from objectively assessing the amount of weight that is being applied to a lower limb.

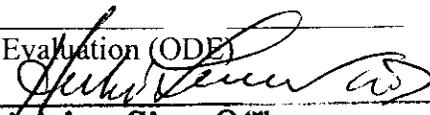
Prescription Use √
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Part 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

510(k) Number _____